

# Stylesheet Prototype: Human Prescription Drug Labeling with Highlights

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use [Proprietary names] safely and effectively. See full prescribing information for [proprietary name].

[PROPRIETARY NAME] ([nonproprietary name])

Dosage form: [Dosage form display name]

Route of administration: [Route of administration display name]  
[DEA schedule display name]

Initial U.S. Approval: [Approval year]

**[Box Warning highlights text is placed here]**

### RECENT MAJOR CHANGES

[Recent major changes highlights text]

### INDICATIONS AND USAGE

[Indications and usage highlights text]

### DOSAGE AND ADMINISTRATION

[Dosage and Administration highlights text]

### DOSAGE FORMS AND STRENGTHS

[Dosage forms and strengths highlights text]

### CONTRAINDICATIONS

[contraindication highlights text]

### WARNINGS AND PRECAUTIONS

[warnings and precautions highlights text]

### ADVERSE REACTIONS

[adverse event highlight text]

To report SUSPECTED ADVERSE REACTIONS, contact ([represented organization name]) at ([assigned entity telecom]) and ([assigned entity telecom]) or [if human prescription drug, then FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)]

### DRUG INTERACTIONS

[drug interaction highlights text]

### USE IN SPECIFIC POPULATIONS

[Use in specific population highlights text]

[Patient counseling information highlights text]

Revised: [effectiveTime]

## FULL PRESCRIBING INFORMATION: CONTENTS[\*]

[Box Warning title [34066-1]

1 INDICATIONS AND USAGE [34067-9]

2 DOSAGE AND ADMINISTRATION [34068-7]

3 DOSAGE FORMS AND STRENGTHS [43678-2]

4 CONTRAINDICATIONS [34070-3]

5 WARNINGS AND PRECAUTIONS [43685-7]

6 ADVERSE REACTIONS [34084-4]

7 DRUG INTERACTIONS [34073-7]

8 USE IN SPECIFIC POPULATIONS [43684-0]

8.1 Pregnancy [42228-7]

8.2 Labor And Delivery [34079-4]

8.3 Nursing Mothers [34080-2]

8.4 Pediatric Use [34081-0]

8.5 Geriatric Use [34082-8]

9 DRUG ABUSE AND DEPENDENCE [42227-9]

9.1 Controlled Substance [34085-1]

9.2 Abuse [34086-9]

9.3 Dependence [34087-7]

10 OVERDOSAGE [34088-5]

11 DESCRIPTION [34089-3]

12 CLINICAL PHARMACOLOGY [34090-1]

12.1 Mechanism Of Action [43679-0]

12.2 Pharmacodynamics [43681-6]

12.3 Pharmacokinetics [43682-4]

13. NONCLINICAL TOXICOLOGY [43680-8]

13.1 Carcinogenesis, Mutagenesis, Impairment Of Fertility [34083-6]

13.2 Animal Toxicology And/Or Pharmacology [34091-9]

14 CLINICAL STUDIES [34092-7]

15 REFERENCES [34093-5]

16 HOW SUPPLIED/STORAGE AND HANDLING [34069-5]

17 PATIENT COUNSELING INFORMATION [34076-0]

\*Sections or subsections omitted from the full prescribing information are not listed

## FULL PRESCRIBING INFORMATION

**Highlights Data Elements**

Established Pharmacological Class			
Substance	Mechanism of Action	Physiologic Effect	Structural Class

Indications and Usage						
Indication				Usage		
Indication	Highlights text	Intent of use	Maximum Dose	Use category	Precondition category	Precondition
				Condition of use		
				Limitation of use		

Interaction and Adverse Reactions			
Labeling Section	Consequence	Contributing Factor	Type of Consequence
Interactions			
Adverse reactions			

**Drug Listing Data Elements**

[Part n of n]			
[Proprietary name] [(nonproprietary name)]			
Product Information			
Product code	Route of Administration	Dosage Form	DEA Schedule

Ingredients		
Name (active moiety)	Type	Strength

Imprint information			
Characteristic	Appearance	Characteristic	Appearance
Color		Score	
Shape		Symbol	
Imprint code		Coating	
Size			

Packaging			
#	NDC	Package Description	Multilevel Packaging